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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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COHEN, PONTANI, LIEBERMAN & PAVANE LLP
551 FIFTH AVENUE
SUITE 1210
NEW YORK, NY 10176

EXAMINER	
JEAN-LOUIS, SAMIRA JM	

ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,540	PERC ET AL.	
	Examiner	Art Unit	
	SAMIRA JEAN-LOUIS	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-32 and 34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-32 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/14/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

This Office Action is in response to the amendment submitted on 09/18/08. Claims 18-32 and 34 are currently pending in the application, with claim 33 having being cancelled. Accordingly, claims 18-32 and 34 are being examined on the merits herein.

Receipt of the aforementioned amended claims and IDS is acknowledged and has been entered.

Applicant's argument with respect to the rejection of claims 18-28 and 31-32 has been fully considered but is not found persuasive. Morris et al. clearly teach pharmaceutical formulations in the form of tablets comprising coated olanzapine that is added to a blender along with other excipients, diluents, disintegrants, binders, and lubricants and blended (i.e. homogeneously mixed) and subsequently compressed with the appropriate tooling on tablet compression equipment (see Morris, pg. 8, lines 35-40). Thus, it is the Examiner's contention that the olanzapine tablet produced by the method of Morris is homogeneously mixed given that olanzapine was blended with the appropriate additives and then compressed in the form of tablets. Thus, absent a clear definition from applicant what a homogeneous mixture entails and given the broad interpretation of "homogeneous mixture", the Examiner maintains that the tablet of

Morris et al. is indeed a homogeneous mixture which therefore anticipates applicant's invention.

Moreover, it is unclear to the Examiner what constitute a homogenous mixture as Applicant has failed to define such term in both the specification and in the Arguments to the Non-Final Rejection. Instead, applicant merely argues that it is evident from the specification that the prior art formulation is different from the instant invention given that the prior art utilizes a coated active agent as compared to the instant invention. Such arguments are moot as the claims do not commensurate in scope with applicant's arguments. Consequently, the Examiner asserts that given that Morris et al. teach the use of a coated olanzapine that is blended along with additives and then compressed into a tablet, such mixture is indeed a homogeneous mixture. Further, the Examiner contends where the prior art shows identical products, it is incumbent upon Applicant to show that the claimed product differs from that of the prior art. Mere allegations of non Equivalence are not sufficient. *In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).* Thus, the rejection of claims 18-28 and 31-32 under 35 U.S.C. § 102 (b) are therefore maintained.

Applicant's contention that Nakajima does not remedy the deficiency of Morris has been fully considered. Applicant further argues that the PCT Examination authority along with the EPO have recognized the claims as being novel and comprising an inventive step. Such arguments are not found persuasive as Nakajima et al. was provided to demonstrate that magnesium stearate is known as a glidant in the art.

Given that Morris et al. teach addition of magnesium stearate in his formulation, Morris et al. inherently teach addition of glidants to his compositions. As for applicant's arguments on the novelty of the instant invention, the Examiner would like to point out that U.S. practice differs from that of WIPO and The EPO. Consequently, findings by the EPO and WIPO have no bearings on U.S. Patent laws. Moreover, it is the Examiner's contention that Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

Applicant's argument with respect to the rejection of claims 29-30 under 35 U.S.C. § 103 (a) has been fully considered but is not found persuasive. As previously stated, the Examiner contends that Morris et al. teach 16.3% of cellulose less than the 20 to 30% claimed by applicant. However, it is well within the purview of the skilled artisan to adjust the concentration and range of such components depending on the desired tablet. Thus, Morris as evidenced by Nakajima et al. does indeed render obvious applicant's invention. Thus, the rejection of claims 18-28 and 31-32 under 35 U.S.C. § 103 (a) are therefore maintained.

For the foregoing reasons, the rejections of record remain proper and are restated below for applicant's convenience. However, in view of applicant's amendment, the following 103 (a) Final rejection is being made.

IDS

The information disclosure statement filed on August 14, 2008 (specifically item DE 69718731 T2) fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18-28 and 31-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Morris et al. (EP 0 830 858 A1, previously cited) as evidenced by Nakajima et al. (U.S. 3,926,817, previously cited).

Morris et al. teach an oral formulation where the active ingredient olanzapine is subcoated and mixed with acceptable excipients (instant claim 18, see abstract and pg. 2, lines 49). The anhydrous form of olanzapine (see pg. 2, lines 54-55) was found to

overcome the undesirable discoloration problems of the prior art and found to be stable due to the subcoating of the active ingredient (see pg. 2, lines 35-37 and line 50). The formulation is preferably in a tablet form (instant claim 32). Morris et al. further teaches that the oral formulation can contain diluents such as lactose, binders such as hydroxypropyl cellulose and microcrystalline cellulose, disintegrants such as crospovidone, and lubricants and glidants such as magnesium stearate (instant claim 18). Morris et al. further teach that the subcoated form II of olanzapine was used (see pg. 7, Preparation 2, Form II, lines 15-23) and mixed with 232.12 mg lactose (i.e. 71.4% of b component or oligosaccharide), 13 mg (i.e. 4%) hydroxypropyl cellulose and 40 mg (i.e. 12.3% binder) microcrystalline cellulose (i.e. a total of 16.3% polysaccharide or component (c) or binders), 16.25 mg of crospovidone (i.e. 5% disintegrant) and 1.63 mg of magnesium stearate (i.e. 0.5% lubricant and glidant) (see instant claims 18-28; see pg. 8, example 3). Importantly, Morris et al. teach that the coated olanzapine is blended (i.e. homogeneously mixed) along with the aforementioned excipients and subsequently compressed with the appropriate tooling on tablet compression equipment (See pg. 8, lines 35-39). Morris et al. do not teach the inclusion of solvent during compression so this meets the limitation of claim 18 of the absence of solvents.

Nakajima et al., on the other hand, have been provided to demonstrate that magnesium stearate is known in the art to be a glidant as well (see col. 8, claim 7).

With regard to Claim 18 which is/are a product by process claim(s), it is the Examiner's contention that the product disclosed by the prior art is identical to the claimed product, even though (it is made by a somewhat different process/the prior art is silent on the method of making). There is no evidence to show that the claimed process imparts any patentable distinction between the claimed product and that of the prior art. When the reference teaches a product that appears to be the same as, or an obvious variant of, the product set forth in a product-by-process claim although produced by a different process. See In re Marosi, 710 F.2d 799, 218 USPQ 289 (Fed. Cir. 1983) and In re Thorpe, 777 F.2d 695, 227 USPQ 964 (Fed. Cir. 1985). See also MPEP § 2113.

Accordingly, the teachings of Morris et al. anticipate claims 18-28 and 31-32.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 29-30 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Morris et al. (EP 0 830 858 A1, previously cited) as evidenced by Nakajima et al. (U.S. 3,926,817, previously cited).

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The Morris and Nakajima references are as discussed above and incorporated by reference herein. Morris et al. do not specifically teach 70-90% weight % of 20-30 weight % of cellulose or 0.2-0.4 weight % of a glidant.

Morris et al., however, do teach approximately16.3% of cellulose (i.e. combined amount of hydroxypropyl cellulose and microcrystalline cellulose) and 0.5% of magnesium stearate which is considered to be both a glidant and a lubricant. Consequently, the Examiner asserts that it is well within the purview of the skill of the artisan at the time of the invention to adjust the concentration and range of the

excipients of the oral formulation during the course of routine experimentation so as to obtain the desirable type of tablet.

While the exact percentage of the excipients are not disclosed by Morris et al., it is generally noted that differences in concentration do not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration or range is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). Given that applicant did not point out the criticality of specific ranges or percentages of the invention, it is concluded that the normal desire of scientists or artisans to improve upon what is already generally known would provide the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to vary the percentages of the glidant and cellulose components of the composition of Morris in order to improve the stability of the tablet formulation. Given that Morris et al. teach an oral formulation of olanzapine with additional excipients such a glidants, binders, disintegrants, lubricants and diluents, one of ordinary skill would have been motivated to vary the components of the excipients of the oral formulation of Morris et al. with the reasonable expectation of providing an improved oral formulation of olanzapine that is stable.

Claim 34 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Morris et al. (EP 0 830 858 A1, previously cited) as evidenced by Nakajima et al. (U.S. 3,926,817, previously cited).

The Morris and Nakajima references are as discussed above and incorporated by reference herein. Morris et al. however do not teach the use of an uncoated olanzapine in the oral formulation.

While Morris et al. teach the use of coated olanzapine in the blended mixture, Morris et al. also teach coated olanzapine as a preferred embodiment (see pg. 5, lines 50-51) suggesting that non-coated olanzapine can also be used in the oral formulations. Moreover, Morris et al. further teach that uncoated tablets stored at ambient conditions in amber, high density polyethylene bottles do not show signs of discoloration after 24 months unless the tablets are exposed to open air then discoloration occurs within 5 days (see pg. 4, lines 45-48). Thus, it would be within the skilled artisan to formulate the tablets as uncoated tablets if the intended use is for rapid usage of the formulation before the discoloration period and/or for rapid dissolution.

Thus, to one of ordinary skill in the art at the time of the invention would have found it obvious to utilize the uncoated olanzapine in the composition of Morris if the desire is for rapid dissolution or the intention is for rapid usage before the discoloration time period. Thus, in view of the teachings of Morris et al., one of ordinary skill would have been motivated to utilize the uncoated olanzapine in the oral formulation of Morris et al. with the reasonable expectation of providing an oral formulation of olanzapine that rapidly disintegrate and available for fast usage.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samira Jean-Louis whose telephone number is 571-270-3503. The examiner can normally be reached on 7:30-6 PM EST M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. L. /

Examiner, Art Unit 1617

12/31/2008

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1617